DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 7, 2014

WHPM, INC.
C/O JOE SHIA
LSI INTERNATIONAL INC.
504 EAST DIAMOND AVE. SUITE F
GAITHERSBURG, MD 20877

Re: K142353
Trade/Device Name: First Sign Drug of Abuse Dip Card Test
First Sign Drug of Abuse Cup Test
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine & Cocaine Metabolite test system
Regulatory Class: Class II
Product Code: DIO, DKZ and LDJ
Dated: August 15, 2014
Received: August 21, 2014

Dear Mr. Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k142353

Device Name
First Sign™ Drug of Abuse Cup Test
First Sign™ Drug of Abuse Dip Card Test

Indications for Use *(Describe)*
First Sign™ Drug of Abuse Tests are immunochromatographic assays for the qualitative determination of Amphetamine (d-amphetamine), Cocaine (Benzoylecgonine), and Marijuana (11-nor-Δ9-THC-9-COOH) in human urine at cut-off concentrations of 1000 ng/mL, 300 ng/mL, and 50 ng/mL, respectively. The tests are available in a Cup format and a Dip Card format.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
k142353

1. Date: September 22, 2014

2. Submitter
W.H.P.M., Inc.
5358 Irwindale Ave.
Irwindale, CA 91706

3. Contact person:
John Wan
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4. Device Name: First Sign™ Drug of Abuse Cup Test
First Sign™ Drug of Abuse Dip Card Test

Classification: Class II

Product Code	CFR #	Panel
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology
DKZ	21 CFR, 862.3100 Amphetamine Test System	Toxicology
LDJ	21 CFR, 862.3870 Cannabinoid Test System	Toxicology

5. Predicate Devices:
K052115
First Check Multi Drug Cup 12

6. Intended Use
First Sign™ Drug of Abuse Tests are immunochromatographic assays for the qualitative determination of Amphetamine (d-amphetamine), Cocaine (Benzoylecgonine), and Marijuana (11-nor-Δ9-THC-9-COOH) in human urine at cut-off concentrations of 1000 ng/mL, 300 ng/mL, and 50 ng/mL, respectively. The tests are available in a Cup format and a Dip Card format.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method.

Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

7. Device Description

First Sign™ Drug of Abuse Tests are immunochromatographic assays. Each assay test is a lateral flow system for the qualitative detection of cocaine, amphetamine, and marijuana in human urine. The products are single-use in vitro diagnostic devices, which come in the formats of DipCards or Cups. Each test kit contains a Test Device (in one of the two formats), a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the First Sign™ Drug of Abuse Test and the predicate device is provided in Table 1, Table 2 & Table 3.

Table 1: Features Comparison of First Sign™ Cocaine Test and the Predicate Device

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of cocaine in human urine.	Same
Calibrator	Benzoylecgonine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	300 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Cup, Dip Card	Cup

Table 2: Features Comparison of First Sign™ Amphetamine Test and the Predicate Device

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of amphetamine in human urine.	Same
Calibrator	D-amphetamine	Same
Methodology	Competitive binding, lateral flow	Same

Item	Device	Predicate - K052115
	immunochromatographic assays based on the principle of antigen antibody immunochemistry.	
Specimen Type	Human Urine	Same
Cut-Off Values	1000 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Cup, Dip Card	Cup

Table 3: Features Comparison of First Sign™ Marijuana Test and the Predicate Device

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of marijuana in human urine.	Same
Calibrator	11-nor-Δ9-THC-9 COOH	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	50 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Cup, Dip Card	Cup

9. Test Principle

First Sign™ Drug of Abuse Tests are rapid tests for the qualitative detection of cocaine (benzoylecgonine), amphetamine (D-amphetamine) and marijuana (11-nor-Δ9-THC-9 COOH) in urine samples. Each assay test is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drugs are present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific antibody (monoclonal mouse antibody) coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, at the cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blind-labeled and randomized. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following tables:

Amphetamine (AMP) Dip Card Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot.:I3091168	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**4-/46+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot.: I3091170	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**3-/47+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot.: I3091172	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**3-/47+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**

(AMP) Cup Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot.: I3091169	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**2-/48+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot.: I3091171	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**3-/47+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot.: I3091173	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**1-/49+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**

Cocaine (COC) Dip Card Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot.:I3091168	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**3-/47+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot.: I3091170	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**4-/46+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot.: I3091172	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**3-/47+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**

(COC) Cup Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot.: I3091169	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot.: I3091171	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot.: I3091173	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

Marijuana (THC) Dip Card Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot.:I3091168	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-
Lot.: I3091170	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot.: I3091172	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

THC Cup Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot.: I3091169	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot.: I3091171	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
Lot.: I3091173	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30℃ (39-86^{o}F) for 24 months based on the accelerated stability study at 50℃. Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

A total of 150 samples equally distributed at concentrations of -50% cut-off; -25% cut-off; cut-off; +25% cut-off; +50% cut-off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% cut-off and all negative at and

below -25% cut-off for Amphetamine, Cocaine and Marijuana. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
One Step Amphetamine Test	D-amphetamine	1000
One Step Cocaine Test	Benzoylecogonine	300
One Step Marijuana Test	11-nor-Δ9-THC-9 COOH	50

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and to urine containing target drugs at 25% below and 25% above cut-off levels. These urine samples were tested using three batches of each device for all formats.

Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for different formats.

AMP

4-Acetamidophenol	L-Ephedrine	Oxycodone
Acetophenetidin	(-) Y Ephedrine	Oxymetazoline
N-Acetylprocainamide	Erythromycin	Papaverine
Acetylsalicylic acid	β-Estradiol	Penicillin-G
Aminopyrine	Estrone-3-sulfate	Pentazocaine
Amitryptyline	Ethyl-p-aminobenzoate	Pentobarbital
Amobarbital	Fenfluramine	Perphenazine
Amoxicillin	Fenoprofen	Phencyclidine
Ampicillin	Furosemide	Phenelzine
Ascorbic acid	Gentisic acid	Phenobarbital
Aspartame	Hemoglobin	Phetoin
Atropine	Hydralazine	L-Phenylephrine
Benzilic acid	Hydrochlorothiazide	Phenylpropanolamine
Benzoic acid	Hydrocodone	Prednisolone
Benzoylecgonine	Hydrocortisone	Prednisone
Bilirubin	O-Hydroxyhippuric acid	Procaine
Brompheniramine	3-Hydroxytyramine	Promazine
Caffeine	Ibuprofen	Promethazine
Cannabidiol	Imipramine	D,L-Propanolol
Cannabinol	(-) Isoproterenol	D-Propoxyphene
Chloralhydrate	Isoxsuprine	Quinidine
Chloramphenicol	Ketamine	Quinine
Chlordiazepoxide	Ketoprofen	Ranitidine

Chlorothiazide	Labetalol	Salicylic acid
(±) Chlorpheniramine	Levorphanol	Secobarbital
Chlorpromazine	Loperamide	Sulfamethazine
Chlorquine	Maprotiline	Sulindac
Cholesterol	Meperidine	Temazepam
Clomipramine	Meprobamate	Tetracycline
Clonidine	Methadone	Tetrahydrocortisone
Cocaine hydrochloride	Methylphenidate	Tetrahydrozoline
Codeine	Morphine-3-Dglucuronide	Δ9-THC-COOH
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	D,L-Thyroxine
Dextromethorphan	Niacinamide	Tolbutamine
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	D,L-Octopamine	D, L-Tyrosine
Ecgonine hydrochloride	Oxalic acid	Uric acid
Ecgonine methylester	Oxazepam	Verapamil
(IR,2S)-(-)-Ephedrine	Oxolinic acid	Zomepirac

COC

Acetominophen	Estrone-3-sulfate	Oxymetazoline
Acetophenetidin	Ethyl-p-aminobenzoate	Papaverine
N-Acetylprocainamide	Fenoprofen	Penicillin-G
Acetylsalicylic acid	Furosemide	Pentobarbital
Aminopyrine	Gentisic acid	Perphenazine
Amitryptyline	Hemoglobin	Phencyclidine
Amobarbital	Hydralazine	Phenelzine
Amoxicillin	Hydrochlorothiazide	Phenobarbital
Ampicillin	Hydrocodone	Phentermine
L-Ascorbic acid	Hydrocortisone	L-Phenylephrine
DL-Amphetamine Sulfate	O-Hydroxyhippuric acid	β-Phenylethylamine
Apomorphine	p-Hydroxymethamphetamine	Phenylpropanolamine
Aspartame	3-Hydroxytyramine	Prednisolone
Atropine	Ibuprofen	Prednisone
Benzilic acid	Imipramine	Procaine

Benzoic acid	Iproniazid	Promazine
Benzphetamine	(±) - Isoproterenol	Promethazine
(±) -Brompheniramine	Isoxsuprine	DL-Propranolol
Caffeine	Ketamine	D-Propoxyphene
Cannabidiol	Ketoprofen	D-Pseudoephedrine
Cannabinol	Labetalol	Quinidine
Chloralhydrate	Levorphanol	Quinine
Chloramphenicol	Loperamide	Ranitidine
Chlordiazepoxide	Maprotiline	Salicylic acid
Chlorothiazide	Meperidine	Secobarbital
(±) -Chlorpheniramine	Meprobamate	Serotonin
Chlorpromazine	Methadone	Sulfamethazine
Chlorquine	Methoxyphenamine	Sulindac
Cholesterol	(±) -3,4-Methylene dioxyamphetamine	Temazepam
Clomipramine	hydrochloride(±)-3,4-Methylene- dioxymethamphetamine hydrochloride	Tetracycline
Clonidine	Morphine-3-β-D glucuronide	Tetrahydrocortisone 3-(β-D glucuronide)
Codeine	Morphine Sulfate	Tetrahydrozoline
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	DL-Tyrosine
Dextromethorphan	Niacinamide	Tolbutamide
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	DL-Octopamine	DL-Tryptophan
Ecgonine methylester	Oxalic acid	Tyramine
(-) - Ψ-Ephedrine	Oxazepam	Uric acid
Erythromycin	Oxolinic acid	Verapamil
β-Estradiol	Oxycodone	Zomepirac

THC

4-Acetamidophenol	β-Estradiol	Papaverine
Acetophenetidin	Estrone-3-sulfate	Penicillin-G

N-Acetylprocainamide	Ethyl-p-aminobenzoate	Pentazocine
Acetylsalicylic acid	Fenoprofen	Pentobarbital
Aminopyrine	Furosemide	Perphenazine
Amitryptyline	Gentisic acid	Phencyclidine
Amobarbital	Hemoglobin	Phenelzine
Amoxicillin	Hydralazine	Phenobarbital
Ampicillin	Hydrochlorothiazide	Phentermine
Ascorbic acid	Hydrocodone	L-Phenylephrine
D,L-Amphetamine	Hydrocortisone	β-Phenylethlamine
L-Amphetamine	O-Hydroxyhippuric acid	β-Phenyllethylamine
Apomorphine	3-Hydroxytyramine	Phenylpropanolamine
Aspartame	Ibuprofen	Prednisolone
Atropine	Imipramine	Prednisone
Benzilic acid	Iproniazid	Procaine
Benzoic acid	(-) Isoproterenol	Promazine
Benzoylecgonine	Isoxsuprine	Promethazine
Benzphetamine	Ketamine	D,L-Propanolol
Bilirubin	Labetalol	D-Propoxyphene
Brompheniramine	Levorphanol	D-Pseudoephedrine
Caffeine	Loperamide	Quinidine
Chloralhydrate	Maprotiline	Quinine
Chloramphenicol	Meprobamate	Ranitidine
Chlordiazepoxide	Methadone	Salicylic acid
Chlorothiazide	Methoxyphenamine	Secobarbital
(±) Chlorpheniramine	(+) 3,4-Methylenedioxyamphetamine	Serotonin (5-Hydroxytyramine)
Chlorpromazine	(+)3,4-Methylenedioxymethamphetamine	Sulfamethazine
Chlorquine	Methylphenidate	Sulindac
Cholesterol	Methyprylon	Temazepam
Clomipramine	Morphine-3-β-Dglucuronide	Tetracycline
Clonidine	Nalorphine	Tetrahydrocortisone3 (5-Dglucuronide)
Cocaine hydrochloride	Naloxone	Tetrahydrozoline
Codeine	Nalidixic acid	Thebaine
Cortisone	Naltrexone	Thiamine
(-) Cotinine	Naproxen	Thioridazine
Creatinine	Niacinamide	D, L-Thyroxine
Deoxycorticosterone	Nifedipine	Tolbutamine

Dextromethorphan	Norcodein	Triamterene
Diazepam	Norethindrone	Trifluoperazine
Diclofenac	D-Norpropoxyphene	Trimethoprim
Diflunisal	Noscapine	Trimipramine
Digoxin	D,L-Octopamine	Tryptamine
Diphenhydramine	Oxalic acid	D, L-Tryptophan
Doxylamine	Oxazepam	Tyramine
Ecgonine hydrochloride	Oxolinic acid	PrD, L-Tyrosine
Ecgonine methylester	Oxycodone	Uric acid
(-) Y Ephedrine	Oxymetazoline	Verapamil
Erythromycin	p-Hydroxymethamphetamine	Zomepirac

f. Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device for all formats. The obtained lowest detectable concentration was used to calculate the cross-reactivity. There were no differences observed for different formats.

AMP **(**Amphetamine**, Cut-off=1000 ng/mL)**	**Result** Positive at 1000 ng/mL	**% Cross-Reactivity** 100%
d,1-Amphetamine	Positive at 500 ng/mL	200%
1-Amphetamine	Positive at 100000 ng/mL	1%
(+/-) 3,4-methylene-dioxyamphetamine (MDA)	Positive at 1300 ng/mL	77%
Phentermine	Positive at 100000 ng/mL	1%
Apomorphine	Positive at 50000 ng/mL	2%
β-Phenylethlamine	Positive at 25000 ng/mL	4%
Tyramine	Positive at 10000 ng/mL	10%
Tryptamine	Positive at 25000 ng/mL	4%
d-Methamphetamine	>100000	<1%
l-Methamphetamine	>100000	<1%
ephedrine	>100000	<1%

3,4-Methylenedioxyethylamphetamine (MDEA)	>100000	<1%

COC (Benzoylecogonine**, Cut-off=300 ng/mL)**	**Result** Positive at 300 ng/mL	**% Cross-Reactivity** 100%
Cocaine HCl	Positive at 500 ng/mL	60%
Cocaethylene	>100000	Not detected
Ecgonine	>100000	Not detected

THC (Cannabinoids**, Cut-off=50 ng/mL)**	**Result** Positive at 50 ng/mL	**% Cross-Reactivity** 100%
11-hydroxy-Δ9-Tetrahydrocannabinol	Positive at 15000 ng/mL	0.3%
Δ8- Tetrahydrocannabinol	Positive at 8000 ng/mL	0.6%
Δ9- Tetrahydrocannabinol	Positive at 7000 ng/mL	0.7%
Cannabinol	>200000	Not detected
Cannabidiol	>200000	Not detected

g. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples with a range of 1.000 to 1.030 specific gravity or urine samples with a range of pH 4 to 9 were spiked with target drugs at 25% below and 25% above cut-off levels. These samples were tested using three batches of each device for all formats. Results were all positive for samples at and above +25% cut-off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different formats.

2. Comparison Studies

The method comparison studies for the First Sign™ Drug Tests (Cup and Dip Card) for Amphetamine, Cocaine and Marijuana were performed in-house with three different laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

AMP

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	10	26
	Negative	10	10	19	4	0
Viewer B	Positive	0	0	1	11	26
	Negative	10	10	19	3	0
Viewer C	Positive	0	0	1	12	26
	Negative	10	10	19	2	0

Discordant Results of AMP Dip Card

Viewer	Sample Number	GC/MS Result	Dipcard Format Viewer Results
Viewer A	92410741	883	Positive
Viewer B	92410218	870	Positive
Viewer C	92410218	870	Positive
Viewer A	92410789	1125	Negative
Viewer A	92410801	1119	Negative
Viewer A	92410205	1086	Negative
Viewer A	92410909	1086	Negative
Viewer B	92410789	1125	Negative
Viewer B	92410801	1119	Negative
Viewer B	92410909	1086	Negative
Viewer C	92410801	1119	Negative
Viewer C	92410205	1086	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	1	12	26

	Negative	10	10	19	2	0
Viewer C	Positive	0	0	0	13	26
	Negative	10	10	20	1	0

Discordant Results of AMP Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	92410741	883	Positive
Viewer B	92410209	971	Positive
Viewer A	92410801	1119	Negative
Viewer B	92410205	1086	Negative
Viewer B	92410801	1119	Negative
Viewer C	92410789	1125	Negative

COC

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	10	26
	Negative	10	10	19	4	0
Viewer B	Positive	0	0	1	10	26
	Negative	10	10	19	4	0
Viewer C	Positive	0	0	0	11	26
	Negative	10	10	20	3	0

Discordant Results of COC DipCard

Viewer	Sample Number	GC/MS Result	DipCard Format Viewer Results
Viewer A	92410950	261	Positive
Viewer B	92410950	261	Positive
Viewer A	92410940	347	Negative
Viewer A	92410942	356	Negative
Viewer A	92410941	362	Negative
Viewer A	92410947	357	Negative
Viewer B	92410940	347	Negative
Viewer B	92410942	356	Negative
Viewer B	92410941	362	Negative
Viewer B	92410947	357	Negative

Viewer	Sample Number	GC/MS Result	DipCard Format Viewer Results
Viewer C	92410942	356	Negative
Viewer C	92410941	362	Negative
Viewer C	92410947	357	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	12	26
	Negative	10	10	19	2	0
Viewer B	Positive	0	0	0	12	26
	Negative	10	10	20	2	0
Viewer C	Positive	0	0	1	13	26
	Negative	10	10	19	1	0

Discordant Results of COC Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	92410824	285	Positive
Viewer C	92410950	261	Positive
Viewer A	92410961	335	Negative
Viewer A	92410941	362	Negative
Viewer B	92410941	362	Negative
Viewer B	92410942	356	Negative
Viewer C	92410941	362	Negative

THC

DipCard format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	14	26
	Negative	10	10	18	0	0
Viewer B	Positive	0	0	1	14	26

	Negative	10	10	19	0	0
Viewer C	Positive	0	0	1	14	26
	Negative	10	10	19	0	0

Discordant Results of THC DipCard

Viewer	Sample Number	GC/MS Result	DipCard Format Viewer Results
Viewer A	92410924	43	Positive
Viewer A	92410995	47	Positive
Viewer B	92410995	47	Positive
Viewer C	92410995	47	Positive

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	26
	Negative	10	10	19	0	0
Viewer B	Positive	0	0	0	14	26
	Negative	10	10	20	0	0
Viewer C	Positive	0	0	1	14	26
	Negative	10	10	19	0	0

Discordant Results of THC Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	92410924	43	Positive
Viewer C	92410181	42	Positive

Lay-user study

A lay user study was performed at three intended user sites with 280 lay persons testing the amphetamine devices, 280 lay persons testing the cocaine devices and 280 lay persons testing the marijuana devices. A total of 140 females and 140 males tested the amphetamine samples, 138 females and 142 males tested cocaine samples, and 139 females and 141 males tested the marijuana samples. They had diverse educational and professional backgrounds and ranged in age from 21 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled.

Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below.

Comparison between GC/MS and Lay Person Results (AMP DipCard)

% of Cutoff	Number of samples	AMP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	246	0	20	100%
-50% Cutoff	20	492	0	20	100%
-25% Cutoff	20	738	1	19	95%
+25% Cutoff	20	1267.5	18	2	90%
+50% Cutoff	20	1521	20	0	100%
+75% Cutoff	20	1774.5	20	0	100%

Comparison between GC/MS and Lay Person Results (AMP Cup)

% of Cutoff	Number of samples	AMP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	246	0	20	100%
-50% Cutoff	20	492	0	20	100%
-25% Cutoff	20	738	2	18	90%
+25% Cutoff	20	1267.5	19	1	95%
+50% Cutoff	20	1521	20	0	100%
+75% Cutoff	20	1774.5	20	0	100%

Comparison between GC/MS and Lay Person Results (COC DipCard)

% of Cutoff	Number of samples	COC Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	71	0	20	100%
-50% Cutoff	20	142.5	0	20	100%
-25% Cutoff	20	213.75	3	17	85%
+25% Cutoff	20	379	19	1	95%
+50% Cutoff	20	454.5	20	0	100%
+75% Cutoff	20	530	20	0	100%

Comparison between GC/MS and Lay Person Results (COC Cup)

% of Cutoff	Number of samples	COC Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	71	0	20	100%
-50% Cutoff	20	142.5	0	20	100%
-25% Cutoff	20	213.75	2	18	90%
+25% Cutoff	20	379	20	0	100%
+50% Cutoff	20	454.5	20	0	100%
+75% Cutoff	20	530	20	0	100%

Comparison between GC/MS and Lay Person Results (THC DipCard)

% of Cutoff	Number of samples	THC Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	12	0	20	100%
-50% Cutoff	20	24.5	0	20	100%
-25% Cutoff	20	36.75	1	19	95%
+25% Cutoff	20	64.25	20	0	100%
+50% Cutoff	20	77	20	0	100%
+75% Cutoff	20	90	20	0	100%

Comparison between GC/MS and Lay Person Results (THC Cup)

% of Cutoff	Number of samples	THC Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	12	0	20	100%
-50% Cutoff	20	24.5	0	20	100%
-25% Cutoff	20	36.75	1	19	95%
+25% Cutoff	20	64.25	19	1	95%
+50% Cutoff	20	77	20	0	100%
+75% Cutoff	20	90	20	0	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

   Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that the First Sign™ Drug of Abuse Dip Card Test and First Sign™ Drug of Abuse Cup Test are substantially equivalent to the predicate.